

Robert Greene Sterne
Edward Kessler
Jorge A. Goldstein
David S. Cornwell
Robert W. Esmond
Tracy-Gene G. Durkin
Michele A. Cimbala
Michael B. Ray
Robert E. Sokohl
Eric K. Steffe
Michael Q. Lee
Steven R. Ludwig
John M. Covert
Linda E. Alcorn
Robert C. Millonig
Lawrence B. Bugaisky
Donald J. Featherstone
Michael V. Messinger

Judith U. Kim
Timothy J. Shea, Jr.
Patrick E. Garrett
Jeffrey T. Helvey
Heidi L. Kraus
Albert L. Ferro*
Donald R. Banowitz
Peter A. Jackman
Teresa U. Medler
Jeffrey S. Weaver
Kendrick P. Patterson
Vincent L. Capuano
Eldora Ellison Floyd
Thomas C. Fiala
Brian J. Del Buono
Virgil Lee Beaston
Theodore A. Wood
Elizabeth J. Haanes

Joseph S. Ostroff
Frank R. Cottingham
Christine M. Lhullier
Rae Lynn Prengaman
George S. Bardmesser
Daniel A. Klein*
Jason D. Eisenberg
Michael D. Specht
Andrea J. Kamage
Tracy L. Muller
LuAnne M. DeSantis
Ann E. Summerfield
Tiera S. Coston
Aric W. Ledford*
Helene C. Carlson
Timothy A. Doyle
Jessica L. Parezo
Gaby L. Longworth*

Lori A. Gordon*
Nicole D. Dretar*
Ted J. Ebersole
Jyoti C. Iyer*
Laura A. Vogel

Registered Patent Agents*
Karen R. Markowicz
Nancy J. Leith
Matthew J. Dowd
Aaron L. Schwartz
Katrina Yujian Pei Quach
Bryan L. Skelton
Robert A. Schwartzman
Teresa A. Colella
Jeffrey S. Lundgren
Victoria S. Rutherford
Michelle K. Holoubek

Robert H. DeSelms
Simon J. Elliott
Julie A. Heider
Mita Mukherjee
Scott M. Woodhouse
Michael G. Penn
Christopher J. Walsh

Of Counsel
Kenneth C. Bass III
Evan R. Smith
Marvin C. Guthrie

*Admitted only in Maryland
*Admitted only in Virginia
*Practice Limited to
Federal Agencies

July 27, 2004

WRITER'S DIRECT NUMBER:
(202) 772-8851

INTERNET ADDRESS:
RSCHWART@SKGF.COM

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Art Unit 1614

Re: U.S. Utility Patent Application
Application No. 10/816,893; Filed: April 5, 2004
For: **Substituted N'-(Arylcarbonyl)-Benzhydrazides, N'-(Arylcarbonyl)-Benzylidene-hydrazides and Analogs as Activators of Caspases and Inducers of Apoptosis and the Use Thereof**
Inventors: Cai *et al.*
Our Ref: 1735.0560002/RWE/RAS

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. Five (5) page of Form PTO-1449 citing twenty-four (24) references;
3. First Supplemental Information Disclosure Statement;
4. Two (2) page of Form PTO-1449 citing seven (7) references; and
5. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Robert A. Schwartzman, Ph.D.
Agent for Applicants
Registration No. 50,211

RWE/RAS/law
Enclosures

Sterne, Kessler, Goldstein & Fox P.L.L.C. : 1100 New York Avenue, NW : Washington, DC 20005 : 202.371.2600 f202.371.2540 : www.skgf.com

292172v1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Cai *et al.*

Appl. No.: 10/816,893

Filed: April 5, 2004

For: **Substituted N'-(Arylcarbonyl)-
Benzhydrazides, N'-(Arylcarbonyl)-
Benzylidenhydrazides and Analogs
as Activators of Caspases and
Inducers of Apoptosis and the Use
Thereof**

Confirmation No.: 3966

Art Unit: 1614

Examiner: *To be assigned*

Atty. Docket: 1735.0560002/RWE/RAS

Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450
Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents **AA1-AJ1** are not provided in accordance with the U.S. Patent and Trademark Office pre-OG notice of July 11, 2003, which states "[t]he Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003."

Copies of all other documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. 10/141,769, Cai *et al.*, filed May

10, 2002, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached Form PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants advise that, to the best of Applicants' knowledge and belief, each of the following substituted hydrazides were available from one or more commercial suppliers or were otherwise known prior to May 10, 2001, when Applicants' priority application, U.S. Appl. No. 60/289,803 was filed:

N'-(2-Phenoxypyridine-3-carbonyl)-4-nitrobenzhydrazide
N'-(2-Phenoxypyridine-3-carbonyl)-3-(trifluoromethyl) benzhydrazide
N'-(2-Phenoxypyridine-3-carbonyl)-3-amino-benzhydrazide
N'-(2-Phenoxypyridine-3-carbonyl)-2-amino-5-nitrobenzhydrazide
N'-(5-(1-hexynyl) pyridine-3-carbonyl)-3-(trifluoromethyl)-benzhydrazide
N'-(pyridine-3-carbonyl)-4-bromobenzhydrazide
N'-(2-Phenoxypyridine-3-carbonyl)-2-methylaminobenzhydrazide
N'-(2-Phenoxypyridine-3-carbonyl)-2-aminobenzoylhydrazide

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not

be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

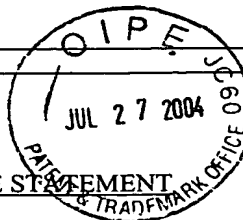
Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Robert A. Schwartzman, Ph.D.
Agent for Applicants
Registration No. 50,211

Date: 7/27/04
1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600
291644_1.DOC



FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1735.0560002/RWE/RAS
FIRST NAMED INVENTOR
Cai *et al.*
FILING DATE
April 5, 2004

APPLICATION NO.
10/816,893

ART UNIT
1614

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	5,281,619	01/25/1994	Dell <i>et al.</i>			03/22/1993
	AB1	5,741,818	04/21/1998	Dimmock			06/07/1995
	AC1	5,753,649	05/19/1998	Tahara <i>et al.</i>			08/30/1996
	AD1	5,981,531	11/09/1999	Brewster <i>et al.</i>			05/29/1998
	AE1	6,130,217	10/10/2000	Arnold <i>et al.</i>			09/20/1995
	AF1	6,225,323	05/01/2001	Yatscoff <i>et al.</i>			04/10/1998
	AG1	6,281,211	08/28/2001	Cai <i>et al.</i>			02/04/1999
	AH1	6,323,228	11/27/2001	BaMaung <i>et al.</i>			09/15/2000
	AI1	2002/0061886	05/23/2002	Wang <i>et al.</i>			12/06/2001
	AJ1	2002/0128292	09/12/2002	Cai <i>et al.</i>			12/07/2001
	AK						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WO 00/07017	02/10/2000	WIPO			Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	1	Qian, X., and Zhang, R., "Syntheses and Insecticidal Activities of Novel 2,5-Disubstituted-1,3,4-oxadiazoles," <i>J. Chem. Technol. Biotechnol.</i> 67:124-130, Blackwell Scientific Publications (1996)
	AS	1	International Search Report for International Patent Application PCT/US02/14722, issued December 2, 2002
	AT	1	Database USPATFULL on STN Accession No. 2000:134884, (Pfizer Inc., New York, NY, USA), "Compounds enhancing antitumor activity of other cytotoxic agents," US Patent No. 6,130,217, Arnold <i>et al.</i> , October 10, 2000

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.
1735.0560002/RWE/RASAPPLICATION NO.
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Cai *et al.*FILING DATE
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>2</u>	Database USPATFULL on STN Accession No. 1999:141938, (Zeneca Limited, London, United Kingdom) "Acid derivatives," US patent 5,981,531, Brewster <i>et al.</i> , November 9, 1999
	AS	<u>2</u>	Database CHEMCATS on STN AN 1998:582475 (Catalog Name Maybridge HTS, Order Number BTB 03108), Chemical Name N'3-(2-aminobenzoyl)-2-phenoxy pyridine-3-carbohydrazide (3 April 2000)
	AT	<u>2</u>	Database CHEMCATS on STN AN 1998:582476 (Catalog Name Maybridge HTS, Order Number BTB 03109), Chemical Name N'3-[2-(methylamino)benzoyl]-2-phenoxy pyridine-3-carbohydrazide (3 April 2000)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>3</u>	Database CHEMCATS on STN AN 1998:582469 (Catalog Maybridge, Order Number BTB 03099) Chemical Name N ³ -(2-amino-5-nitrobenzoyl)-2-phenoxy pyridine-3-carbohydrazide (3 April 2000)
	AS	<u>3</u>	Database CHEMCATS on STN AN 1998:582468 (Catalog Maybridge, Order Number BTB 03098) Chemical Name N ³ -(2-amino-5-chlorobenzoyl)-2-phenoxy pyridine-3-carbohydrazide (3 April 2000)
	AT	<u>3</u>	Database CHEMCATS on STN AN 1998:582456 (Catalog Maybridge, Order Number BTB 03075) Chemical Name N ³ -[3-(trifluoromethyl)benzoyl]-2-phenoxy pyridine-3-carbohydrazide (3 April 2000)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.
1735.0560002/RWE/RASAPPLICATION NO.
10/816,893FIRST NAMED INVENTOR
Cai *et al.*FILING DATE
April 5, 2004ART UNIT
1614**U.S. PATENT DOCUMENTS**

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FOREIGN PATENT DOCUMENTS

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>4</u>	Database CHEMCATS on STN AN 1998:582454 (Catalog Maybridge, Order Number BTB 03073) Chemical Name N ³ -(4-nitrobenzoyl)-2-phenoxy pyridine-3-carbohydrazide (3 April 2000)
	AS	<u>4</u>	Database CHEMCATS on STN AN 1998:582455 (Catalog Maybridge, Order Number BTB 03074) Chemical Name N ³ -[(2-phenoxy-3-pyridyl)carbonyl]-2-phenoxy pyridine-3-carbohydrazide (3 April 2000)
	AT	<u>4</u>	Database CHEMCATS on STN AN 1998:633657 (Catalog Name Maybridge HTS, Order Number BTB 03957), Chemical Name N ³ -(2,6-difluorobenzoyl)-6-(4-chlorophenoxy)pyridine-3-carbohydrazide (30 May 2002)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENTATTY. DOCKET NO.
1735.0560002/RWE/RASAPPLICATION NO.
10/816,893FIRST NAMED INVENTOR
*Cai et al.*FILING DATE
April 5, 2004ART UNIT
1614

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	5	Database CHEMCATS on STN AN 1998:633656 (Catalog Maybridge HTS, Order Number BTB 03956) Chemical Name N'3-(4-chlorobenzoyl)-6-(4-chlorophenoxy)pyridine-3-carbohydrazide (30 May 2002)
	AS		
	AT		

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



In re application of:

Cai *et al.*

Appl. No.: 10/816,893

Filed: April 5, 2004

For: **Substituted N'-(Arylcarbonyl)-
Benzhydrazides, N'-(Arylcarbonyl)-
Benzylidenehydrazides and Analogs
as Activators of Caspases and
Inducers of Apoptosis and the Use
Thereof**

Confirmation No.: 3966

Art Unit: 1614

Examiner: *To be assigned*

Atty. Docket: 1735.0560002/RWE/RAS

First Supplemental Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450
Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicants' Information Disclosure Statement filed herewith, in connection with the above-captioned application.

The Examiner is respectfully requested to consider the cited document as well as the art cited therein during examination.

Copies of documents **AK1** and **AA2-AF2** are not provided in accordance with the U.S. Patent and Trademark Office pre-OG notice of July 11, 2003, which states "[t]he Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each

cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003."

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached Form PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

Cai *et al.*
Appl. No. 10/816,893

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

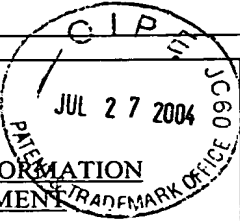
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Robert A. Schwartzman, Ph.D.
Agent for Applicants
Registration No. 50,211

Date: 7/27/04
1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600
292130_1.DOC

Page 1 of 2



FORM PTO-1449

**FIRST SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT**

ATTY. DOCKET NO.
1735.0560002/RWE/RAS
 FIRST NAMED INVENTOR
Cai *et al.*
 FILING DATE
April 5, 2004

APPLICATION NO.
10/816,893

 ART UNIT
1614

U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
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	AJ						
	AK1	2003/0045581	03/06/2003	Cai <i>et al.</i>			06/03/2002

FOREIGN PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
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	AS		
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EXAMINER	DATE CONSIDERED
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

292122_1.DOC

FORM PTO-1449

**FIRST SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT**

ATTY. DOCKET NO.
1735.0560002/RWE/RAS
FIRST NAMED INVENTOR
Cai *et al.*
FILING DATE
April 5, 2004

APPLICATION NO.
10/816,893
ART UNIT
1614

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	2003/0105140	06/05/2003	Cai <i>et al.</i>			11/19/2002
	AB2	6,613,803	09/02/2003	Wang <i>et al.</i>			10/21/1999
	AC2	6,638,947	10/28/2003	Wang <i>et al.</i>			12/06/2001
	AD2	2003/0225080	12/04/2003	Wang <i>et al.</i>			06/18/2003
	AE2	RE38,425	02/10/2004	Dimmock <i>et al.</i>			04/20/2000
	AF2	6,696,442	02/24/2004	Wang <i>et al.</i>			06/25/2002
	AG						
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes
							No
	AM						Yes
							No
	AN						Yes
							No
	AO						Yes
							No
	AP						Yes
							No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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EXAMINER			
DATE CONSIDERED			

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.